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Standardization Policies

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COMMON DEFINITIONS AND TERMINOLOGY IN MARKET SURVEILLANCE

Note by the secretariat

The Working Party on Regulatory Cooperation and Standardization Policies, at its eighteenth session, decided to “resume work on common definitions and terminology initiated by the project on Market Surveillance Definitions.” (ECE/TRADE/C/WP.6/2008/18, paragraph 70).

This document provides a list of these terms and definitions. It is intended to promote a common understanding of and to harmonize such terms and definitions used in national legislation.

It is submitted to the Working Party for consideration and discussion.

I INTRODUCTION

1. This list of terms and definitions relevant to market surveillance and post-market surveillance of non-food products is intended to promote a common understanding of and harmonize the terms and definitions used in national legislation.
2. A first version of this document was circulated to WP.6 Bureau, and has been discussed in a teleconference that took place on 31 March 2009, as well as at the meeting of WP.6 Bureau, rapporteurs and coordinators, "START" Team and "MARS" Group, that took place in Stockholm, from 27 to 29 May 2009. Comments made by the participants in the teleconference and the Stockholm meeting been considered in the preparation of the current version.
3. In particular, some definitions from the WTO/TBT Agreement have been included and the term "state" is no longer used. In line with the European Communities' legal framework for marketing of products, the scope of this document is restricted to the surveillance of non-food products that are or have been placed on the market (market and post-market surveillance).
4. Delegations are invited to submit additional terms that they believe should be included in this list and any deviating definition from their national legislation of the terms listed. The latter may foster a better understanding of the differences in legislation and market surveillance responsibilities and activities among the members.

II. SCOPE OF THE DOCUMENT

5. The terms in this guide are taken (and sometimes adapted) from the WTO/TBT Agreement, EC legislative instruments and ISO guides and standards. Although ISO guides and standards are not mandatory, some terms and definitions from these publications have been included to clarify their use in legislative texts and in as far as they do not contradict to the use of those terms in the legislative texts referenced.

Term	Reference	Definition	Notes	Status	ID
Authority		Central or local government body, or non-governmental body empowered by government to perform public tasks			
Authorized representative	adapted from: 765/2008/EC, art 2 (4)	Any natural or legal person established within a country who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant legislation			
Conformity assessment	ISO17000:2004,2.1	Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled	Conformity assessment includes activities such as: testing and inspection.		
Conformity assessment procedures	WTO/TBT 3.	Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled	Conformity assessment procedures include, <i>inter alia</i> , procedures for sampling, testing and inspection, evaluation, verification and assurance of conformity; registration, accreditation and approval, as well as their combinations.		
Country		Territory occupied by a nation under a central government	In the case of a treaty establishing a free trade area, "country" may refer to the combined territory occupied by the states that have acceded to the treaty		

Term	Reference	Definition	Notes	Status	ID
Distributor	765/2008/EC, art 2 (6)	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market			
Economic operators	765/2008/EC, art 2 (7)	The manufacturer, the authorised representative, the importer and the distributor			
Government body (central —)	WTO/TBT 6	Central government, its ministries and departments and any body subject to the control of the central government in respect of the activity in question			
Government body (local —)	WTO/TBT 7	Government other than a central government (e.g. states, provinces, Länder, cantons, municipalities), its ministries or departments or any body subject to the control of such a government in respect of the activity in question			
Governmental body (non- —)	adapted from WTO/TBT 8	Body other than a central government body or a local government body			

Term	Reference	Definition	Notes	Status	ID
Hazard	ISO51, 3.5	Potential source of harm	The term hazard can be qualified in order to define its origin or the nature of the expected harm (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).		

Term	Reference	Definition	Notes	Status	ID
Importer	adapted from: 765/2008/EC, art 2 (5)	Any natural or legal person established within a country who places a product from another country on the market			
Inspection	ISO17000:2004,4.3	Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements			
Jurisdiction		The territory within which an authority can exercise power			
Manufacturer	765/2008/EC, art 2 (3)	Any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark			
Market (making available on the —)	adapted from: 765/2008/EC, art 2 (1)	Any supply of a product for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge			
Market (placing on the —)	adapted from: 765/2008/EC, art 2 (2)	The first making available of a product on the market			

Term	Reference	Definition	Notes	Status	ID
Market surveillance	adapted from: 765/2008/EC, art 2 (17)	The activities carried out and measures taken by designated authorities to ensure that products comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection			

Term	Reference	Definition	Notes	Status	ID
Market surveillance authority	adapted from: 765/2008/EC, art 2 (18)	Authority responsible for carrying out market surveillance within its jurisdiction			
Procedure	ISO 9000:2000,3.4.5	Specified way to carry out an activity or a process			
Producer	adapted from 2001/95/EC, art 2 (e)	<p>(a) the manufacturer of the product and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;</p> <p>(b) the manufacturer's representative, when the manufacturer is not established in the country or, if there is no representative established in the country, the importer of the product;</p> <p>(c) other professionals in the supply chain, insofar as their activities may affect the safety properties of a product</p>			
Product	ISO 9000:2000, 3.4.2	Result of a process			

Term	Reference	Definition	Notes	Status	ID
Product (consumer →)	2001/95/EC, art 2 (a)	Any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.	This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.		

Term	Reference	Definition	Notes	Status	ID
Product (dangerous —)	2001/95/EC, art 2 (c)	Any product which does not meet the definition of ‘safe product’			
Product (safe —)	2001/95/EC, art 2 (b)	Any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:			
		(a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;	The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be ‘dangerous’.		

Term	Reference	Definition	Notes	Status	ID
Product (safe — (cont'd)	2001/95/EC, art 2 (b)	(b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;			
		(c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; (cont'd)			
		(d) the categories of consumers at risk when using the product, in particular children and the elderly			
Recall	adapted from 2001/95/EC, art 2 (g)	Any measure aimed at achieving the return of a non-complying product that has already been made available on the market			
Risk	ISO73, 3.1.1	Combination of the probability of an event and its consequence	The term “risk” is generally used only when there is at least the possibility of negative consequences.		
Risk (serious —)	adapted from 2001/95/EC, art 2 (d)	Any risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities			
Risk assessment	ISO73, 3.3.1	Overall process of risk analysis and risk evaluation			

Term	Reference	Definition	Notes	Status	ID
Risk communication	ISO73, 3.2.4	Exchange or sharing of information about risk between the decision-maker and other stakeholders	The information can relate to the existence, nature, form, probability, severity, acceptability, treatment or other aspects of risk.		
Risk control	ISO73, 3.4.2	Actions implementing risk management decisions			
Risk management	ISO73, 3.1.7	Coordinated activities to direct and control an organization with regard to risk	Risk management generally includes risk assessment, risk treatment, risk acceptance and risk communication.		
Safety	ISO51, 3.1	Freedom from unacceptable risk			
Sampling	ISO17000:2004,4.1	Provision of a sample of the object of conformity assessment, according to a procedure			
Standard	WTO/TBT 2.	Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method	Although the international standardization community generally prepares standards based on consensus, the WTO/TBT Agreement also covers documents that are not based on consensus.		

Term	Reference	Definition	Notes	Status	I D
Technical regulation	WTO/TBT 1.	Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method			
Technical specification	765/2008/EC, art 2 (8)	A document that prescribes technical requirements to be fulfilled by a product, process or service			
Testing	ISO17000:2004,4.2	Determination of one or more characteristics of an object of conformity assessment, according to a procedure			
Use (intended —)	ISO51, 3.13	Use of a product, process or service in accordance with information provided by the supplier			
Use (reasonably foreseeable mis- —)	ISO51, 3.14	Use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour			

Withdrawal	adapted from 2001/95/EC, art 2 (h)	Any measure aimed at preventing the distribution, display and offer of a non- complying product			
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References:

- [1] WTO/TBT Agreement, Annex 1: Terms and their definitions for the purpose of this Agreement” (http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf - page 132)
- [2] ISO 9000:2005: Quality management systems - Fundamentals and vocabulary
- [3] ISO 17000:2004: Conformity assessment -- Vocabulary and general principles
- [4] ISO Guide 51:1999: Safety aspects -- Guidelines for their inclusion in standards
- [5] ISO Guide 73:2002: Risk management -- Vocabulary -- Guidelines for use in standards
- [6] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002)
- [7] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218. 13.08.2008)

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